

## REMARKS

In the final Office Action dated July 29, 2003, all of the pending claims, claims 18-30 and 45-79, were rejected either under 35 U.S.C. §102(b) as being anticipated by or under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,360,444 to Kusuhara. Of the pending claims, claims 18, 45, 58, and 70 are independent.

By this Amendment, Applicants have amended claims 18, 45, and 70. Support for these amendments can be found at least, for example, in Figs. 9, 17, and 21, and in the corresponding written description of those figures.

Kusuhara discloses an occluder supporter for installation in the valve of a heart and a method of attaching the supporter. Referring to the exemplary embodiment of Fig. 1, Kusuhara discloses an occluder supporter 1 for assisting in closing a valve 2. The supporter 1 has a support 7 and stitched attachments 5, 5. As shown in Figs. 2 and 3, the supporter 1 is configured to be placed on the atrial side of a bicuspid valve 2 with the stitched attachments 5, 5 attached to contralateral edges 4, 4 of the bicuspid valve 2. The support 7 transects the valve aperture 6. Col. 4, lines 14-17, 20-24, and 44-49. The other exemplary embodiments of Figs. 4-10 disclosed by Kusuhara similarly are attached to edges of heart valves.

Each of independent claims 18, 45, and 58 is directed to a method of treating an in situ heart valve, and independent claim 70 is directed to a method of improving cardiac function. Claim 18 recites, among other things, "providing a first elongate member having a first end and a second end and an anchor assembly at each of the first and second ends" and "anchoring the anchor assembly at the second end to a portion of the heart spaced from the valve."

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In the final Office Action, the Examiner equates the stitched attachments 5, 5 of Kusuhara with Applicants' recited anchor assemblies. Office Action at p. 2. As discussed above, however, Kusuhara teaches that stitched attachments 5, 5 are attached to contralateral edges of the valve. Therefore, Kusuhara neither discloses nor otherwise suggests, and indeed teaches against, "anchoring the anchor assembly at the second end to a portion of the heart spaced from the valve," as recited in claim 18. For at least this reason, therefore, claim 18 is patentably distinguishable from Kusuhara.

Similarly, Kusuhara fails to disclose or otherwise suggest "altering a geometry of a heart chamber at a location spaced from the in situ heart valve," as recited in claim 45, "positioning a device with respect to a heart such that . . . a portion of the device contacts and alters a geometry of structure other than structure of the in situ heart valve," as recited in claim 58, or "placing a first member relative to a heart chamber and spaced from an in situ valve," as recited in claim 70. For at least these reasons, each of claims 45, 58, and 70 also is patentably distinguishable from Kusuhara.

In the Office Action, the Examiner asserts that

at least a portion of the anchor assemblies 5 or 25 being anchored to a heart wall surrounding a heart chamber would have been immediately obvious, if not inherent, because the material properties of said anchor assemblies (column 4, lines 26-43) would have impelled the ordinary practitioner to implant the device in a manner as to avoid contact with the valve leaflets and thus to prevent with leaflet movement and to reduce the possibility of tissue trauma.

Office Action at pages 2-3.

The Examiner provides no support for these various conclusory assertions regarding the obviousness or inherency of anchoring at least a portion of the stitched

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attachments 5 or 25 of Kusuhara to a heart wall, and as such, the Examiner has failed to set forth a *prima facie* case.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, three basic criteria must be satisfied. First, “there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine reference teachings.” M.P.E.P. § 2143. “Second, there must be a reasonable expectation of success.” Id. Third, “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” Moreover, “[t]he teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant’s disclosure.” M.P.E.P. § 2143 (citing In re Vaeck, 947 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 1991)).

Under the guidance of the M.P.E.P., the obviousness rejection based on Kusuhara is improper since the Examiner has not set forth any suggestion or motivation having a basis in the cited reference or any other source. There is no *prima facie* case of obviousness since one of ordinary skill in the art would not have been motivated to modify Kusuhara in the manner suggested by the Examiner. This is because, among other reasons, to attach the stitched attachments 5, 25 of Kusuhara other than to the contralateral edges of the valve, as proposed by the Examiner, would destroy Kusuhara’s explicit teaching regarding the attachment of those elements. When a proposed modification changes the principles of operation explicitly taught in a reference, such a modification is insufficient to render the claims *prima facie* obvious. See M.P.E.P. § 2143.01.

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Further, rather than supplying motivation found in a reference or other source, the Examiner presents conclusory assertions regarding the modification of Kusuhara and appears to rely on hindsight and the teaching of Applicants' own disclosure in order to modify the cited reference. Such practice is completely contrary to the existing state of the law of obviousness. Analogous to a somewhat recent Federal Circuit decision,

[t]he examiner's conclusory statements . . . do not adequately address the issue of motivation . . . . This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to [modify a reference] simply to "[use] that which the inventor taught against its teacher."

In re Lee, 61 U.S.P.Q.2d 1430 at 1434 (Fed. Cir. Jan. 18, 2002) (citation omitted).

Similarly, to the extent the Examiner asserts there is some inherent disclosure in Kusuhara, the Examiner must show that "the missing descriptive matter is *necessarily* present" in the reference. See M.P.E.P. §2112 (*quoting In re Robertson*, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999)). "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. §2112 (emphasis in original.) In the present case, the Examiner has not established that Kusuhara's disclosure of stitched attachments 5 or 25 attached to edges of a valve is necessarily a teaching of "at least a portion of the anchor assemblies 5 or 25 being anchored to a heart wall surrounding a heart chamber," as asserted by the Examiner. Indeed, the teachings in Kusuhara regarding stitched attachments 5 or 25 are not necessarily a teaching of such anchoring alleged by the Examiner since Kusuhara explicitly teaches attaching the stitched attachments 5 or 25 to edges of the valve and not to any other portion of the heart.

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To the extent the Examiner is relying on specific facts within his personal knowledge regarding his assertions of obviousness and inherency in the Office Action at page 3, Applicants request that the Examiner supply a personal affidavit setting forth specific facts within his personal knowledge that support those assertions regarding Kusuhara, in accordance with 37 C.F.R. § 1.104(d)(2) and M.P.E.P. §2144.03, if he maintains the rejection of the claims based on Kusuhara.

For at least the above reasons, claims 18, 45, 58, and 70, and their respective dependent claims, 19-30, 46-57, 59-69, and 71-79, are patentably distinguishable from Kusuhara, and thus the rejections based on Kusuhara should be withdrawn.

Claims 19-30, 46-57, 59-69, and 71-79 depend from one of claims 18, 45, 58, and 70, and therefore are patentable for at least the same reasons each of claims 18, 45, 58, and 70 is patentable. In addition, at least some of the dependent claims recite unique features and combinations that distinguish from the cited art and therefore at least some also are separately patentable.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 18-30 and 45-79 in condition for allowance. Applicants submit that the proposed amendments do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner. This Amendment should allow for immediate action by the Examiner.

Furthermore, Applicants respectfully point out that the final action by the Examiner presented some new arguments as to the application of the art against Applicants' invention. It is respectfully submitted that the entering of the Amendment

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would allow the Applicants to reply to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of the Amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

Applicants request the entry of this Amendment, the withdrawal of the outstanding claim rejections, and the timely allowance of claims 18-30 and 45-79.

The Office Action contains characterizations of the claims and art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: October 28, 2003

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